510(k) SUMMARY

This Summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements of 21CFR §807.81(a)(3).

The assigned 510(K) number is : K061992

A. Submitter's information

SEP 19 2006

Company: EPS Bio Technology Corp.
Address: 2F, No. 49-2, Lane 2, Guang Fu Rd., Sec.2 Hsinchu City, Taiwan, R.O.C.
Contact Name: Mr. Y.C. Lei, General Manager
Phone: 886-3-5752522
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Date Prepared: June 30, 2006

B. Purpose for Submission:
The Indication for use and fundamental scientific technology of the modified device has not changed. The changes are modified mechanical appearance of device, test range, test time and the labeling.

C. Measurand:
Glucose

D. Type of Test:
Quantitative; electrochemical biosensor

E. Proprietar y and Established Names:
EasyPlus Self Monitoring Glucose Test System

F. Common or Usual Name:
Glucose Test System

G. Regulatory Information:

1. Regulation section:
   21 CFR 862.1345, Glucose Test System
   21 CFR 862.1660, Quality control material (assayed and unassayed).

2. Classification:
   Class II
   Class I, reserved

3. Product code:
   NBW, System Test, Blood Glucose, Over the Counter

CGA, Glucose Oxidase, Glucose
JJX, Single (Specified) Analyte Controls (Assayed and Unassayed)

4. Panel:
Chemistry 75

H. Intended Use:

1. Intended use(s):
see Indications for Use below

2. Indication(s) for use:

The EasyPlus Self-Monitoring Blood Glucose System is used by individuals with diabetes. It is for the quantitative measurement of glucose levels in fresh capillary whole blood from fingerstick, as an aid in monitoring the effectiveness of diabetes management in the home and in clinical settings.

3. Special conditions for use statement(s):
N/A

4. Special instrument requirements:
N/A

I. Device Description:

The EasyPlus Self Monitoring Blood Glucose System is comprised of the EasyPlus Blood Glucose Meter, EasyPlus Glucose Test Strips, Auto Lancet, Check strip, code card and control solutions.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Easy Pain Supreme Self Monitoring Blood Glucose System

2. Device Company
EPS Bio Technology Corporation

3. Predicate 510(k) number(s):
k043245

4. Comparison with predicate:

Similarities		
Item	Device	Predicate
Detection method	Amperometry	Amperometry
Enzyme	Glucose oxidase (Aspergillus niger)	Glucose oxidase (Aspergillus niger)
Mediator	Potassium ferricyanide	Potassium ferricyanide

Similarities		
Item	Device	Predicate
Electrode	Carbon electrode	Carbon electrode
Hematocrit range	30-55%	30-55%
Sample volume	≥ 2.0 uL	≥ 2.0 uL
Temperature range	10-40^{0}C	10-40^{0}C
Humidity range	R.H. ≤ 90%	R.H. ≤ 90%
Coding	Code card	Code card
Memory capability	100 tests with date and time	100 tests with date and time
Power	1.5V (AAA) batteries	1.5V (AAA) batteries
Battery life	Approx. 1000 tests	Approx. 1000 tests

Differences		
Item	Device	Predicate
Test range	30-550 mg/dL	40-600 mg/dL
Test time	5 seconds	25 seconds
Size L x W x H (inch)	3.2"x 2"x 0.7"	2.9"x 2.1"x 0.7"
Weight	1.6 oz (without batteries)	1.8 oz (without batteries)

K. Standard/Guidance Document Referenced (if applicable):

1. CLSI EP5-A, Precision Performance of Clinical Chemistry Devices
2. CLSI EP6-P, Evaluation of the Linearity of Quantitative Analytical Methods; Proposed Guideline
3. CLSI EP7-P, Interference Testing in Clinical Chemistry; Proposed Guideline
4. ISO 15197:2003, In Vitro Diagnostic Test Systems – Requirements for Blood Glucose Monitoring Test Systems for Self Managing Diabetes Mellitus
5. IEC 60601-1-2, Medical Electrical Equipment – Part 1: General Requirement for Safety; Electromagnetic Compatibility – requirements and Tests
6. IEC 61010-1, Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use – Part 1: General Requirements
7. IEC 60601-2-101, Safety Requirements For Electrical Equipment for Measurement, Control, and Laboratory Use – Part 2-101: Particular Requirements for In Vitro Diagnostic (IVD) Medical Equipment
8. IEC 60068-2-64, Environmental Testing- Part 2: Test Methods- Test Fh: Vibration, Broad-band Random (Digital Control) and Guidance
9. IEC 61326 (2002-02) – (for reference), Electrical Equipment for Measurement Control, and Laboratory Use – EMC Requirements
10. ISO 14971:2000, Medical Devices – Application of Risk Management to Medical Devices
11. ISO 15223:2000, Medical Devices – Symbols to be Used With Medical Device Labels, Labeling, and Information to be Supplied
12. EN 376:2002, Information Supplied by the Manufacturer With In Vitro Diagnostic Reagents for Self Testing
13. ISO 10993-1, Biological Evaluation of Medical Devices – Part 1:Evaluation and Testing

14. EN 13640:2002 Stability Testing of In Vitro Diagnostic Reagents

L. Test Principle:

The EasyPlus Self Monitoring Blood Glucose System employs a disposable dry reagent strip technology, based on the glucose oxidase method for glucose determination. Each test strip features an electrode containing the enzyme glucose oxidase (Aspergillus niger). A blood sample is applied to the blood collection area at the tip of the strip and is automatically drawn into the reaction zone, where the glucose oxidase catalyzes the oxidation of glucose to produce gluconic acid. During the reaction, a mediator transfers electrons to the electrode surface and generates a current. The amount of the current is proportional to the amount of glucose present in the blood sample. The glucose concentration is displayed on the meter screen after 5 seconds.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Within-run – Testing was conducted by taking 4 mL of blood that was treated with heparin through a vacuum tube. Glucose was added to the 4 mL of blood to generate 6 different levels of glucose concentration for the test. Each of the samples was measured 10 times. The glucose concentration ranges were: 30-50 mg/dL, 51-110 mg/dL, 111-150 mg/dL, 151-250 mg/dL, 251-400 mg/dL, and 401~550 mg/dL.

Range(mg/dL)	N	EasyPlus		
		mean(mg/dL)	SD(mg/dL)	CV(%)
30~50 mg/dL	200	56.3	3.5	6.2
51~110 mg/dL	200	100.0	4.5	4.5
111~150 mg/dL	200	134.0	5.6	4.2
151~250 mg/dL	200	189.6	5.2	2.7
251~400 mg/dL	200	313.5	8.9	2.8
401~550 mg/dL	200	479.7	10.4	2.2

Day to day - Three control solutions of Low, Normal and High were prepared. Each of the controls was measured twice a day, once in the morning and once in the afternoon for a month.

Control	n	mean (mg/dL)	SD (mg/dL)	CV (%)
Low	400	59.3	3.0	5.1
Normal	400	131.6	3.5	2.7
High	400	389.3	12.4	3.2

b. Linearity/assay reportable range:

A blood sample of 25 mL was taken, treated with heparin vacuum tube, to be set

for a day. Testing was performed using whole blood supplemented with B-D-glucose to provide samples at seven different blood glucose levels (30-50 mg/dL, 51-80 mg/dL, 81-120 mg/dL, 121-200 mg/dL, 201-300 mg/dL, 301-400 mg/dL, and 400-550 mg/dL). A total of 210 tests were performed using 10 meters among the seven glucose ranges per each strip lot.

The linear regression was as follows:
$y = 0.9722x - 0.1682$, $r^2 = 0.9956$, Syx = 9.38, N = 630

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
Traceability referenced to NIST Standards, and it cleared with predicate device.

d. *Detection limit:*
Data was provided to support a reportable range of 30-550 mg/dL.

e. *Analytical specificity:*
Interference testing was conducted to determine the effect of select endogenous and exogenous substances. A series of test samples, systematically varying in the concentration of the interferents, was prepared by making quantitative, volumetric mixtures of two pools: one at the highest concentration to be tested and the other at the lowest. The substances and concentrations of the interferents are recommended in CLSI EP7-P.
Interference from dopamine and L-dopa was observed when the recommended concentration of these drugs was reached in the blood. Interference was also observed in higher than therapeutic dosages of acetaminophen, gentisic acid, and methyldopa.

f. *Assay cut-off:*
N/A

2. Comparison studies:
   a. *Method comparison with predicate device:*
   Two hundred and five people with diabetes performed a finger stick using the EasyPlus system. A healthcare professional then performed the test on the EasyPlus and the YSI. The range of tested values for these samples was 30-550 mg/dL.

   The linear regressions were as follows:
   Patient vs. YSI: $y = 0.95x + 7.41$, $r^2 = 0.976$
   Healthcare professional vs. YSI: $y = 0.95x + 7.91$, $r^2 = 0.971$

   And compare with predicate device, the linear regressions was as follows:
   EasyPlus vs. predicate device: $y = 0.966x - 3.80$, $r^2 = 0.980$

   b. *Matrix comparison:*
   N/A

3. Clinical studies:
   a. *Clinical Sensitivity:*
      N/A
   b. *Clinical specificity:*
      N/A
   c. Other clinical supportive data (when a. and b. are not applicable):
      see section 2.a.

4. Clinical cut-off:
   N/A

5. Expected values/Reference range:
   Expected blood glucose levels for people without diabetes (refereced from Joslin Diabetes Manual):

Time	Range (mg/dL)	Range (mmol/L)
before breakfast	70-105	3.9-5.8
before lunch or dinner	70-110	3.9-6.1
one hour after meals	less than 160	less than 8.9
two hours after meal	less than 120	less than 6.7
between 2 and 4 AM	greater than 70	greater than 3.9

N. Proposed Labeling:
The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:
The EasyPlus Self Monitoring Blood Glucose System has the same intended use and similar technological characteristics as the Easy Pain Supreme Self Monitoring Blood Glucose System (k043245) marketed by EPS Bio Technology Corp., Moreover, bench testing contained in the submission demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the EasyPlus Self-Monitoring Blood Glucose System is substantially equivalent to the predicate devise.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Y.C. Lei
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Hsinchu City, Taiwan, China

SEP 19 2006

Re: k061992
Trade/Device Name: EasyPlus Self-Monitoring Blood Glucose System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW, CGA, JJX
Dated: August 18, 2006
Received: August 21, 2006

Dear Mr. Lei:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061992

Device Name: EasyPlus Self-Monitoring Blood Glucose System

Indications For Use:

The **EasyPlus Self-Monitoring Blood Glucose System** is used by individuals with diabetes. It is for the quantitative measurement of glucose levels in fresh capillary whole blood from fingerstick, as an aid in monitoring the effectiveness of diabetes management in the home and in clinical settings.

Prescription Use _____ AND/OR Over-The-Counter Use V

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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